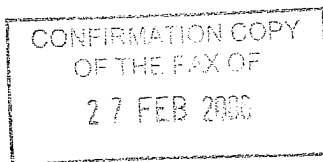


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Winksele, February 27, 2006

Re: International patent application PCT/EP2004/013435  
Filing date: 26 November 2004  
Applicant: Materialise N.V. et al.  
Title: "Method for manufacturing a prosthesis made prior to implant placement"  
Our ref: M3153-PCT/wb/lp/kd

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To the Written Opinion dated January 25, 2006

Dear Mr. Chabus,

We thank you for the informal communication pursuant to Rule 66.6. PCT.

We herewith submit without prejudice a new set of claims (claims 1 to 29) to replace claims 1 to 30 as previously submitted. The new set of claims being based on the previously submitted claims, a copy of the previous claims with the amendments marked thereon is also submitted.

Please find hereunder a detailed account of the amendments as well as our arguments in response to the comments formulated under Item V in the Written Opinion.

## I. Amendments

Claim 1 has been amended in that it now further clarifies the order of magnitude of the lateral movements envisaged within the context of the present application. Support for this amendment can be found on page 10, line 31 to page 11, line 29. In this passage, the principle of a flat-to-flat connection is explained. More particularly, it is detailed in the section on page 11, lines 11 to 29, that even if a tolerance interlock is provided on the flat surface, this should be such that this interlock *“allows lateral movements of about 0.4 to about 1.4 mm.”* (page 11, line 19). Thus it is clear that, even in the presence of the tolerance interlock, the principle of the flat-to-flat surface is to allow significant lateral movements. This is further supported by the description in its description of the size of the neck of the retaining screw on page 10, lines 28-30: *“According to a particular embodiment, the different diameter between the neck of the retaining screw and the opening in the anchorage part of the prosthesis varies between 0,4 and 1,4mm”*. Again, this supports the fact that the present combination is envisaged to allow a lateral movement of about 0,4 to about 1,4 mm.

To avoid any misunderstanding, claim 3 has been amended to no longer refer to the tolerance provided, as this tolerance is in fact inherent to claim 1, as it is provided in the difference in diameter between the neck of the retaining screw and the anchorage part of the prosthesis.

Claim 18 has been amended with the same limitation to the order of magnitude of the allowed lateral movements.

## II. Arguments in reply to the objections presented under item V in the Written Opinion

The Examiner has indicated that claim 1 as filed does not meet the criteria of Article 33(1) PCT as it does not involve an inventive step over document D1 and D5. It is respectfully submitted that the amendment to claim 1 further clarifies the difference between present invention and the cited documents.

D1 describes a combination of dedicated implant or implant assembly, prosthesis and retaining screw, allowing angular compensations. It should be noted that this is different from lateral compensations, as possible with the flat-to-flat connection of the present invention, in that these lateral compensations allow a compensation as to the position relative to the implant, a feature not possible with angular compensations. This allows the simultaneous appropriate placement of multiple implants and immediate loading of a pre-manufactured prosthesis and implant combination, which is not feasible if only angular compensations can be made.

The Examiner has indicated that changing the convex-concave surfaces from document D1 to a flat-to flat configuration would be a normal option, since a flat-to-flat connection and the existence of play between fixing screw and the hole of the element to be fixed has already been used in the same technical field, as seen in document D5. Applicant respectfully disagrees.

Document D5 mentions (column 4, lines 51-57): *‘This predetermined and intentional play will allow a dental bridge to be fitted in the mouth cavity even if there is a certain error in relation to the positioning of the distance members in the mouth cavity. The intentional play between gold*

*cylinder and distance member is preferably within the range of 0,05 – 0,2 mm.* However, this amount of play is no more than the inherent fitting tolerances (see column 3, lines 18-19) and is clearly smaller than the substantial tolerances provided by the flat-to-flat surface in the present application. The flat-to-flat or interlock connections of the present invention provide for significant lateral movements of the prosthesis to allow for compensation of errors in the “immediate loading” procedure for which this system has been specifically developed (see background section page 2, lines 8-31), in which the position of the implants in the mouth of the patient is not known at the time of the production of the prosthesis, but is predicted by means of an implant planning. In order to further clarify this, the range of the lateral movements allowed by the combination of the present invention has been included in claim 1, to demonstrate that this is not about ‘inherent fitting tolerances’ but in fact relates to ‘lateral movements’ of a different magnitude.

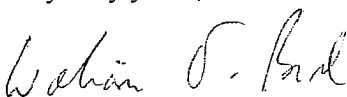
While the invention in D5 focuses on the use of a conical screw in the making of an impression and does not illustrate the final fitting of the prosthesis or “gold cylinder” referred to, it is submitted that from the above it is clear that document D5 does not envisage substantial lateral movements of this gold cylinder with regard to the distance member and, in the absence of a flat-to-flat surface, and in the absence of a neck of the retaining screw which is substantially tapered compared to the opening in the basis of the prosthesis, such a lateral movement would not be possible. There is no indication in either D5 nor in D1 that such lateral movements are desirable, and thus, it is respectfully submitted that the combination of D5 and D1 neither discloses the motivation, nor the solution to obtain such lateral movements.

It is further submitted that the additional feature provided in claim 3, that the neck of the screw is also smaller in diameter than its threaded shaft, provides for the additional advantage that the screw can be used for centering the prosthesis upon placement on the implant. This is a further difference from what is described in D5, where either a conical screw is used for centering, which does not allow any lateral movement, or, in the final fitting of the prosthesis, a traditional screw is used (which may allow for some fitting tolerance, but which does not allow for centering). It is submitted that these features of claim 3 introduce yet another difference over the state of the art, which is not suggested in any of the documents cited by the Examiner.

### III. Conclusion

It is respectfully submitted that the enclosed set of claims are novel and inventive over the prior art in accordance with Article 33(2) and (3) PCT. Should the Examiner disagree with any of the above-described amendments, he is cordially invited to contact the undersigned by telephone in accordance with Rule 66 PCT.

Very truly yours,



William E. Bird

encl.:

- new claims 1-29 (version showing amendments) (5 pages)
- new claims 1-29 (clean copy) (5 pages), in triplicate

Amended claims for PCT/EP2004/013435 (version showing amendments)

1. A combination of dedicated dental implant or implant assembly, prosthesis and retaining screw, wherein the anchorage part (1) of the prosthesis comprises a hole (2) for the retaining screw, characterized in that the diameter of the neck (3) of the retaining screw is smaller than the hole in the anchorage part of the prosthesis and further characterized in that the interface of said implant or implant assembly with the anchorage part of prosthesis comprises a flat-to-flat connection, so as to allow, upon fixing of the prosthesis to the implant or implant assembly with retaining screw, compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or implant assembly, by way of lateral movements of the prosthesis on the implant of about 0,4 to about 1,4 mm.
2. The combination according to claim 1, wherein the diameter of the neck (3) of the retaining screw is about 0.4 to 1.2 mm smaller with respect to the diameter of hole (2) in the anchorage part of the prosthesis.
3. The combination of claim 1 or 2, which is further characterized in that the diameter of the neck (3) of the retaining screw is smaller than its threaded shaft (15) ~~so as to provide a tolerance between said neck (3) and the hole (2) in the anchorage part of the prosthesis.~~
4. The combination of claim 3, characterized in that there is no tolerance between the threaded shaft (15) of the retaining screw and the hole (2) in the anchorage part of the prosthesis.
5. The combination of claim 1 or 2, wherein the interface of said implant or implant assembly with the anchorage part of prosthesis is characterized by interlocking features which ensure a tolerance interlock, allowing, upon fixing of the prosthesis to the implant or implant assembly with the retaining screw, compensation for lateral misalignments between the

center of the anchorage part of the prosthesis and the center of the implant or implant assembly.

- 5           6. The combination according to any one of claims 1 to 5, wherein said anchorage part is a separate cylindrical component that can be incorporated into a prosthesis.
- 10          7. The combination according to claim 6, wherein said anchorage part is integral part of the prosthesis.
- 15          8. The combination of any one of claims 1 to 7, wherein said implant is a single structure and said flat-to-flat connection or said tolerance interlock is between the proximal surface of the fixture head (6) of said implant and the proximal surface of the anchorage part of the prosthesis.
- 20          9. The combination of any one of claims 1 to 7, wherein said implant assembly comprises an abutment and said flat-to-flat connection or said tolerance interlock is between the abutment and the anchorage part (1) of the prosthesis.
- 25          10. The combination of any one of claims 1 to 9, wherein said implant has an external surface comprising a distal part (7) which is treated to interface with bone and a proximal part (8) which is untreated, characterised in that the proximal part has a length of between 2 and 6 mm.
- 30          11. The combination of claim 1, wherein the fixture head of said implant at the interface of said implant with the prosthesis having a flat surface, further comprises in said flat surface one or more dedicated features to allow easy extraction of said implant after placement.
12. The combination of claim 1, further comprising an impression coping which comprises an anchorage part with a proximal surface, characterised in that said proximal surface is flat.

13. The combination of claim 1, further comprising an implant replica, characterised in that it comprises a proximal end of which the proximal surface is flat (9) for connection with the anchorage part of said prosthesis or said impression coping having an anchorage part with a proximal flat surface.

14. A dental implant replica characterised in that it comprises a flat-surfaced proximal end (9) for connection with the proximal flat surface of an anchorage part of a prosthesis or an impression coping.

15. The implant replica of claim 14, further comprising one or more flat indentations (10) on its external surface for anchoring into a plaster cast.

16. The implant replica of claim 14, further comprising a tapered distal end (11) for insertion into a resin mould.

17. The implant replica of claim 14, comprising in said flat surface, an opening to an internal threaded hole (12) for introduction of a screw, characterized in that the diameter of the opening and hole are the same size as or smaller than the diameter of the opening in the anchorage part of said prosthesis or impression coping.

18. A retaining screw for fixing a prosthesis to a dental implant or implant assembly having at their interface a flat-to-flat connection or a tolerance interlock, said retaining screw being characterized in that the diameter of its neck (3) is smaller than its threaded shaft (15) and in that the diameter of its neck (3) is about 0.4 to 1.2 mm smaller with respect to the diameter of hole in the anchorage part of the prosthesis, so as to allow, upon fixing of the prosthesis to the implant or implant assembly, compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or implant assembly.

~~19. The retaining screw according to claim 18, characterized in that the diameter of its neck (3) is about 0.4 to 1.2 mm smaller with respect to the diameter of hole in the anchorage part of the prosthesis.~~

5        ~~20.~~19. The retaining screw according to claim 18, further characterized in that it has a cylindrical head (13) with a conical opening inwards (14) to guide the screwdriver into position for screwing.

10       ~~21.~~20. The retaining screw of claim 18, characterized in that the threaded shaft (15) fits into the threaded hole in the implant or implant assembly.

15       ~~22.~~21. The retaining screw of claim 18, characterized in that the diameter of the threaded shaft (15) of the retaining screw is equal to the diameter of the hole (2) in the anchorage part of the prosthesis.

20       ~~23.~~22. A centering screw for fixing a cylindrical component to the implant replica of claim 14 in the production of prosthesis, said centering screw having an externally tapered distal section (16) and having a threaded shaft (17) which fits into the threaded hole (12) of said implant replica.

25       ~~24.~~23. The centering screw of claim ~~23~~22, further characterized in that said externally tapered distal section at its widest part has the same diameter as the inner diameter of the cylindrical component so that the tapered shape ensures centering of the screw with respect to the hole in the anchorage part of said implant replica.

30       ~~25.~~24. An impression coping for taking an impression of a dental implant or implant assembly comprising at its proximal end a flat surface, said impression coping comprising an anchorage part (18) having a flat surface.

~~26.~~25. A burn-out cylinder for connection to the implant replica of claim 14, comprising a proximal end (19) which comprises a flat surface.

~~27.26.~~ The burn-out cylinder of claim ~~26~~25, which further comprises a tapered collar (20).

5        ~~28.27.~~ The burn-out cylinder of claim ~~26~~25, further comprising an internal shaft comprising two cylindrical parts, wherein the diameter of proximal of said two parts is smaller than that of the distal part.

10        ~~29.28.~~ A combination of an impression coping and one or more impression coping screws for fixing to a dental implant or implant replica, said impression coping comprising an internal cylindrical hollow shaft and said impression coping screws comprising a threaded shaft having a diameter corresponding to the diameter of the cylindrical hollow shaft in the impression coping, characterized in that said one or more impression  
15        coping screws can have either a flat cylindrical head with a diameter that is exactly equal to that of the distal part of the coping or a bulbous head with a diameter which larger than that of the distal part of the coping.

20        ~~30.29.~~ The combination according to claim ~~29~~28, wherein said coping impression has a tapered external shape with a concave intrusion circumferentially along the external surface of its proximal part.

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Amended claims for PCT/EP2004/013435 (clean copy)

- 5 1. A combination of dedicated dental implant or implant assembly, prosthesis and retaining screw, wherein the anchorage part (1) of the prosthesis comprises a hole (2) for the retaining screw, characterized in that the diameter of the neck (3) of the retaining screw is smaller than the hole in the anchorage part of the prosthesis and further characterized in that the interface of said implant or implant assembly with the anchorage part of prosthesis comprises a flat-to-flat connection, so as to allow, upon fixing of the prosthesis to the implant or implant assembly with retaining screw, compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or implant assembly, by way of lateral movements of the prosthesis on the implant of about 0,4 to about 1,4 mm.
- 15 2. The combination according to claim 1, wherein the diameter of the neck (3) of the retaining screw is about 0.4 to 1.2 mm smaller with respect to the diameter of hole (2) in the anchorage part of the prosthesis.
- 20 3. The combination of claim 1 or 2, which is further characterized in that the diameter of the neck (3) of the retaining screw is smaller than its threaded shaft (15) .
- 25 4. The combination of claim 3, characterized in that there is no tolerance between the threaded shaft (15) of the retaining screw and the hole (2) in the anchorage part of the prosthesis.
- 30 5. The combination of claim 1 or 2, wherein the interface of said implant or implant assembly with the anchorage part of prosthesis is characterized by interlocking features which ensure a tolerance interlock, allowing, upon fixing of the prosthesis to the implant or implant assembly with the retaining screw, compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant

or implant assembly.

- 5           6. The combination according to any one of claims 1 to 5, wherein said anchorage part is a separate cylindrical component that can be incorporated into a prosthesis.
7. The combination according to claim 6, wherein said anchorage part is integral part of the prosthesis.
- 10          8. The combination of any one of claims 1 to 7, wherein said implant is a single structure and said flat-to-flat connection or said tolerance interlock is between the proximal surface of the fixture head (6) of said implant and the proximal surface of the anchorage part of the prosthesis.
- 15          9. The combination of any one of claims 1 to 7, wherein said implant assembly comprises an abutment and said flat-to-flat connection or said tolerance interlock is between the abutment and the anchorage part (1) of the prosthesis.
- 20          10. The combination of any one of claims 1 to 9, wherein said implant has an external surface comprising a distal part (7) which is treated to interface with bone and a proximal part (8) which is untreated, characterised in that the proximal part has a length of between 2 and 6 mm.
- 25          11. The combination of claim 1, wherein the fixture head of said implant at the interface of said implant with the prosthesis having a flat surface, further comprises in said flat surface one or more dedicated features to allow easy extraction of said implant after placement.
- 30          12. The combination of claim 1, further comprising an impression coping which comprises an anchorage part with a proximal surface, characterised in that said proximal surface is flat.

13. The combination of claim 1, further comprising an implant replica, characterised in that it comprises a proximal end of which the proximal surface is flat (9) for connection with the anchorage part of said prosthesis or said impression coping having an anchorage part with a proximal flat surface.
14. A dental implant replica characterised in that it comprises a flat-surfaced proximal end (9) for connection with the proximal flat surface of an anchorage part of a prosthesis or an impression coping.
15. The implant replica of claim 14, further comprising one or more flat indentations (10) on its external surface for anchoring into a plaster cast.
16. The implant replica of claim 14, further comprising a tapered distal end (11) for insertion into a resin mould.
17. The implant replica of claim 14, comprising in said flat surface, an opening to an internal threaded hole (12) for introduction of a screw, characterized in that the diameter of the opening and hole are the same size as or smaller than the diameter of the opening in the anchorage part of said prosthesis or impression coping.
18. A retaining screw for fixing a prosthesis to a dental implant or implant assembly having at their interface a flat-to-flat connection or a tolerance interlock, said retaining screw being characterized in that the diameter of its neck (3) is smaller than its threaded shaft (15) and in that the diameter of its neck (3) is about 0.4 to 1.2 mm smaller with respect to the diameter of hole in the anchorage part of the prosthesis, so as to allow, upon fixing of the prosthesis to the implant or implant assembly, compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or implant assembly.

19. The retaining screw according to claim 18, further characterized in that it has a cylindrical head (13) with a conical opening inwards (14) to guide the screwdriver into position for screwing.
- 5 20. The retaining screw of claim 18, characterized in that the threaded shaft (15) fits into the threaded hole in the implant or implant assembly.
21. The retaining screw of claim 18, characterized in that the diameter of the threaded shaft (15) of the retaining screw is equal to the diameter of the  
10 hole (2) in the anchorage part of the prosthesis.
22. A centering screw for fixing a cylindrical component to the implant replica of claim 14 in the production of prosthesis, said centering screw having an externally tapered distal section (16) and having a threaded shaft (17)  
15 which fits into the threaded hole (12) of said implant replica.
23. The centering screw of claim 22, further characterized in that said externally tapered distal section at its widest part has the same diameter as the inner diameter of the cylindrical component so that the tapered  
20 shape ensures centering of the screw with respect to the hole in the anchorage part of said implant replica.
24. An impression coping for taking an impression of a dental implant or implant assembly comprising at its proximal end a flat surface, said  
25 impression coping comprising an anchorage part (18) having a flat surface.
25. A burn-out cylinder for connection to the implant replica of claim 14, comprising a proximal end (19) which comprises a flat surface.
- 30 26. The burn-out cylinder of claim 25, which further comprises a tapered collar (20).
27. The burn-out cylinder of claim 25, further comprising an internal shaft

comprising two cylindrical parts, wherein the diameter of proximal of said two parts is smaller than that of the distal part.

5 28. A combination of an impression coping and one or more impression coping screws for fixing to a dental implant or implant replica, said impression coping comprising an internal cylindrical hollow shaft and said impression coping screws comprising a threaded shaft having a diameter corresponding to the diameter of the cylindrical hollow shaft in the  
10 impression coping, characterized in that said one or more impression coping screws can have either a flat cylindrical head with a diameter that is exactly equal to that of the distal part of the coping or a bulbous head with a diameter which larger than that of the distal part of the coping.

15 29. The combination according to claim 28, wherein said coping impression has a tapered external shape with a concave intrusion circumferentially along the external surface of its proximal part.

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